



# Aquatic Animal Drug Approval Workshop

# Status of Aquaculture Drug Approvals

presented  
by

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# Background information



- ▶ Graphs represent AADAP's interpretation and condensation of matrices produced by the National Coordinator for Aquatic New Animal Drug Applications (Ms. Rosalie Schnick)
  - ▶ Matrices in full detail available at:
    - ▶ <http://aquanic.org/jsa/aquadrugs/index.htm> and
    - ▶ <http://www.fws.gov/fisheries/aadap/status.htm>
- ▶ Interpretive methods
  - ▶ categorically assigned a status number to each subsection of the 5 major NADA technical sections (efficacy, target animal safety, environmental safety, human food safety and manufacturing chemistry)
  - ▶ calculated overall estimated percent complete, based on means



# Abbreviations



- ▶ EFF = efficacy technical section (TS)
- ▶ TAS = target animal safety TS
- ▶ MC = manufacturing chemistry TS
- ▶ HFS = human food safety TS
- ▶ ES = environmental safety TS
- ▶ all = all major TS (i.e., EFF, TAS, MC, HFS & ES)
- ▶ NADA = New Animal Drug Application *per se*
- ▶ label = actual approved drug label with associated claims
- ▶ AOI = all other information required for a complete NADA
- ▶ deficient = TS has not been completely accepted by CVM
- ★ = you may be able to generate data to help complete this TS





# Approval Progress for Chloramine-T



BGD in FW salmonids  
External columnaris in walleye

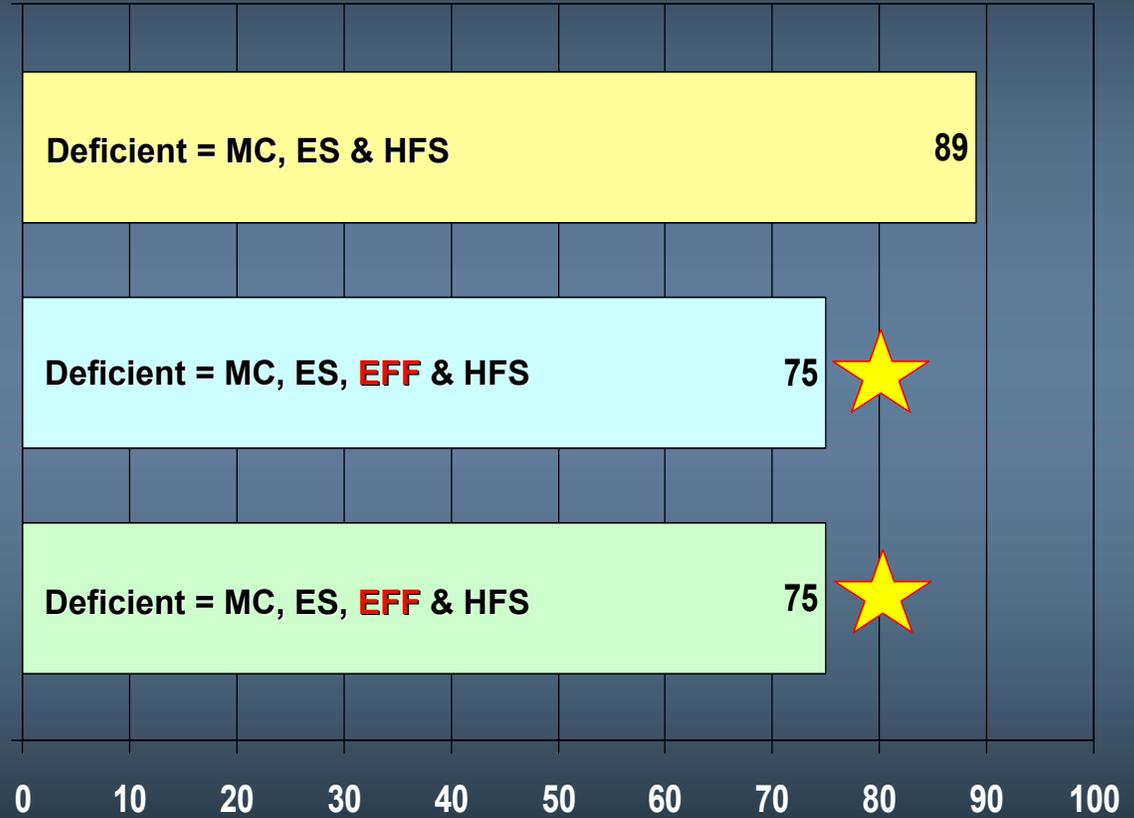
Deficient = MC, ES & HFS 89

External columnaris in all other FW fish

Deficient = MC, ES, **EFF** & HFS 75 ★

BGD in all other FW fish

Deficient = MC, ES, **EFF** & HFS 75 ★



Estimated Percent Complete of Five Major Technical Sections



# Approval Progress for Hydrogen Peroxide



Saprolegnia in all FW fish eggs  
BGD in FW salmonids  
External columnaris in coolwater fish & CC

100

Saprolegnia in all FW fish

Deficient = ES & **EFF**

82



External columnaris in all remaining FW fish

Deficient = ES & **EFF**

83



External protozoa & monogenes in FW fish,  
and control of mortalities from same

Deficient = ES & **EFF**

80



0 10 20 30 40 50 60 70 80 90 100

Estimated Percent Complete of Five Major Technical Sections



# Approval Progress for Oral OTC

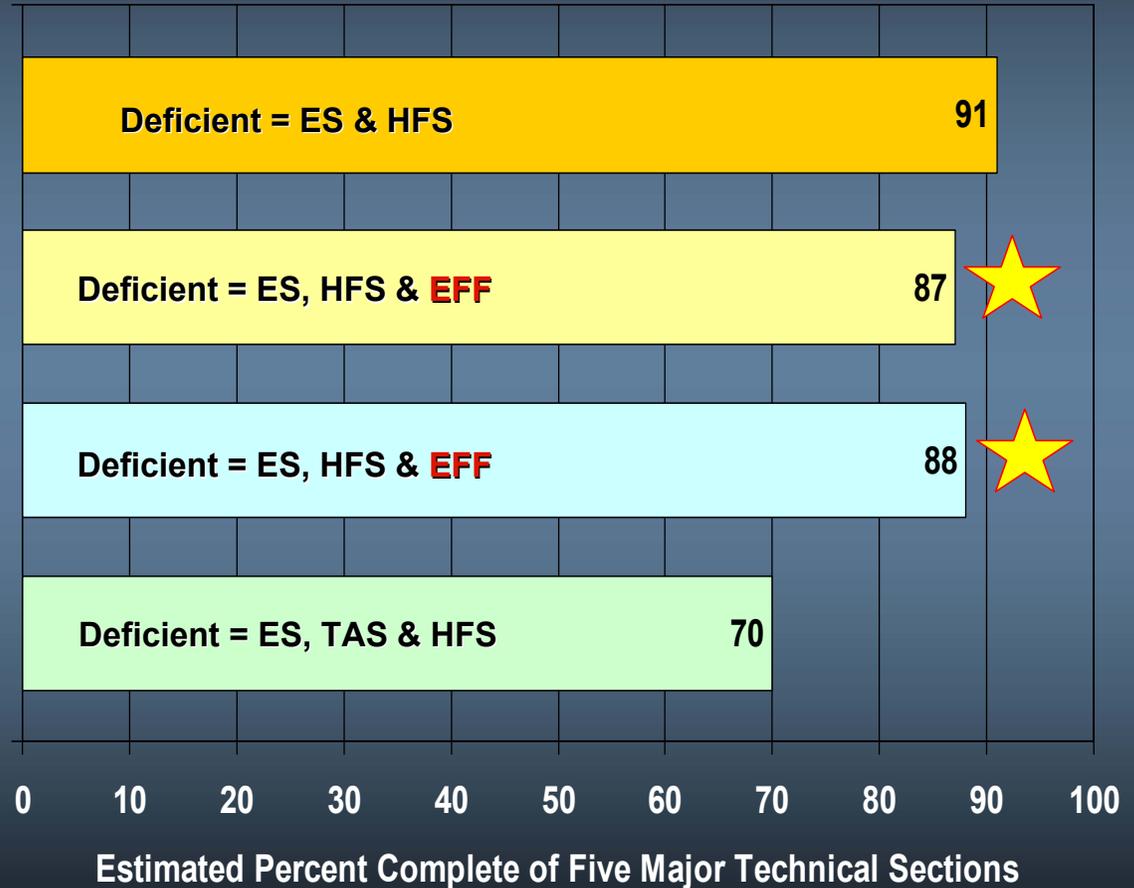


Systemic CWD in FW salmonids  
Systemic columnaris in steelhead

Systemic columnaris in all other FW fish

Motile aeromonas septicemia in FW fish

Necrotizing hepatopancreatitis in shrimp





# Approval Progress for Florfenicol



CWD in FW salmonids  
Furunculosis in FW salmonids

Deficient = ES

93

Systemic columnaris in FW salmonids

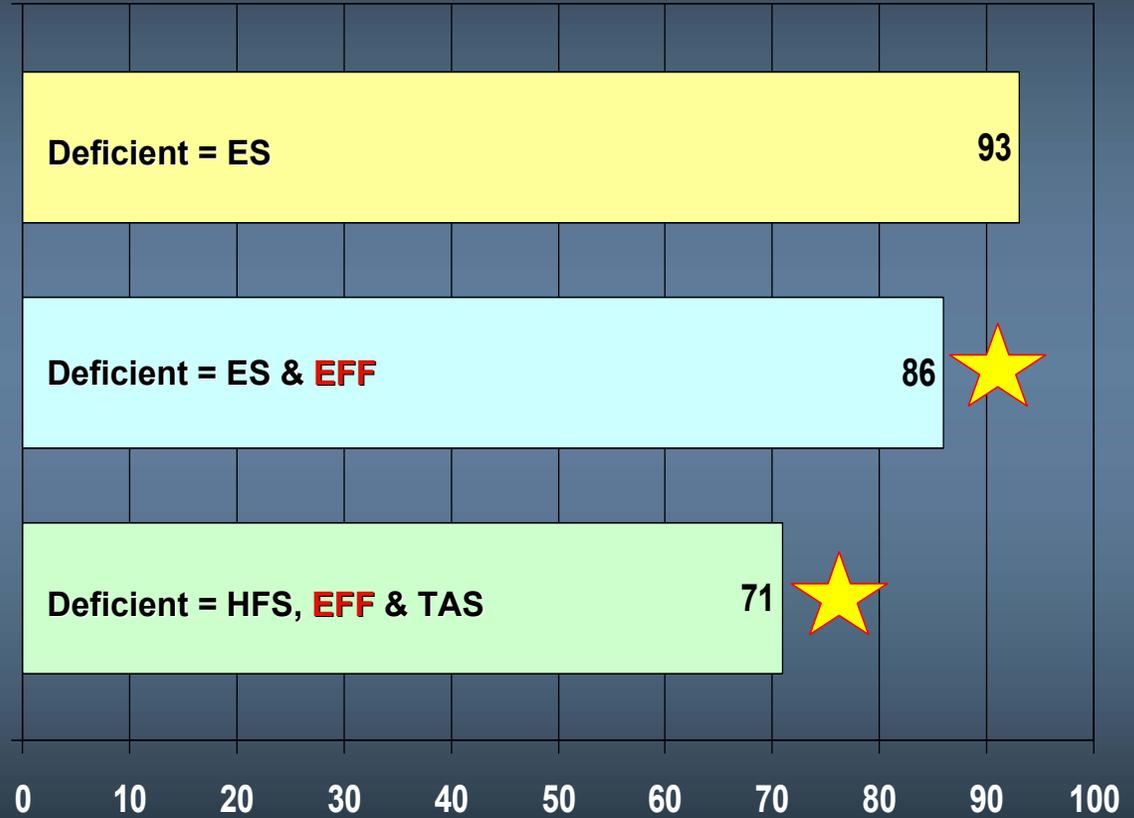
Deficient = ES & **EFF**

86

Systemic columnaris in channel catfish  
Streptococcal infections in tilapia & HSB

Deficient = HFS, **EFF** & TAS

71



Estimated Percent Complete of Five Major Technical Sections



# Approval Progress for AQUI-S®



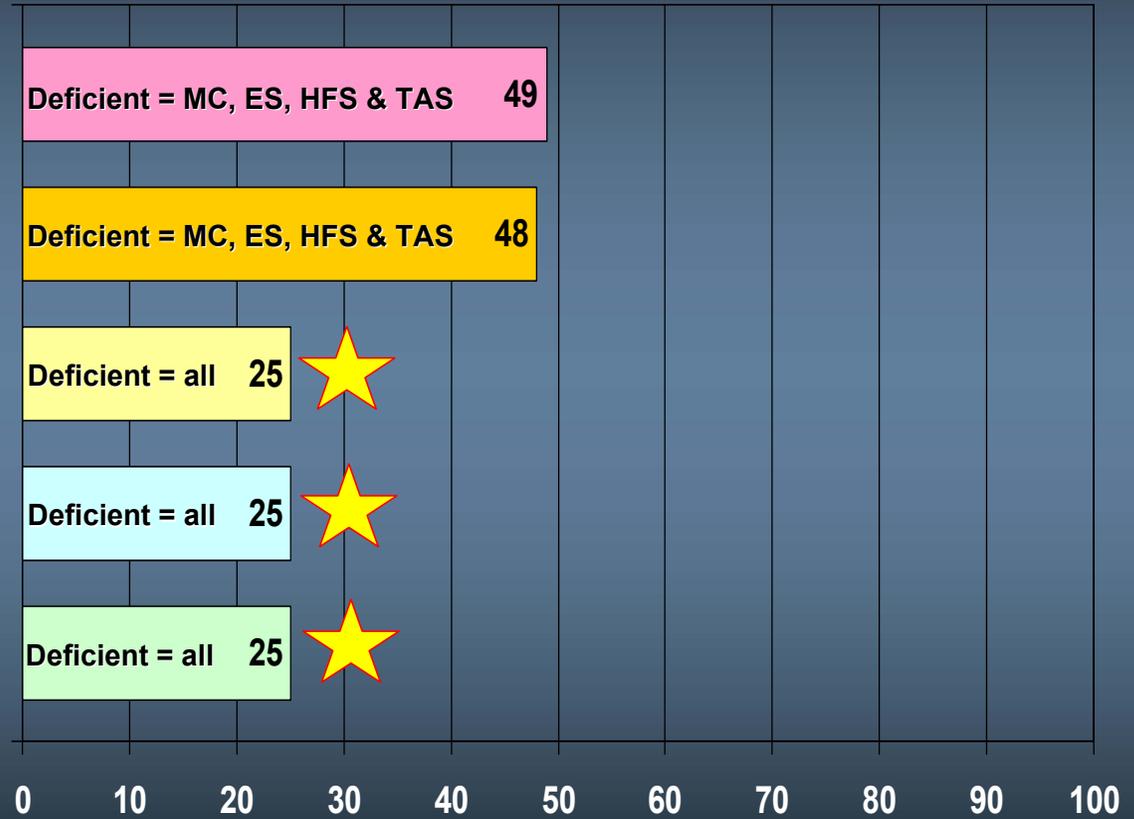
Zero-withdrawal anesthetic for short-term handling of FW salmonids \*

Zero-withdrawal anesthetic for short-term for cool & warmwater FW fish

Zero-withdrawal anesthetic for long-term handling of FW salmonids \* #

Zero-withdrawal anesthetic for long-term handling of cool & warmwater FW fish

Zero-withdrawal anesthetic for short-term handling of marine fish and shellfish \* #



Estimated Percent Complete of Five Major Technical Sections

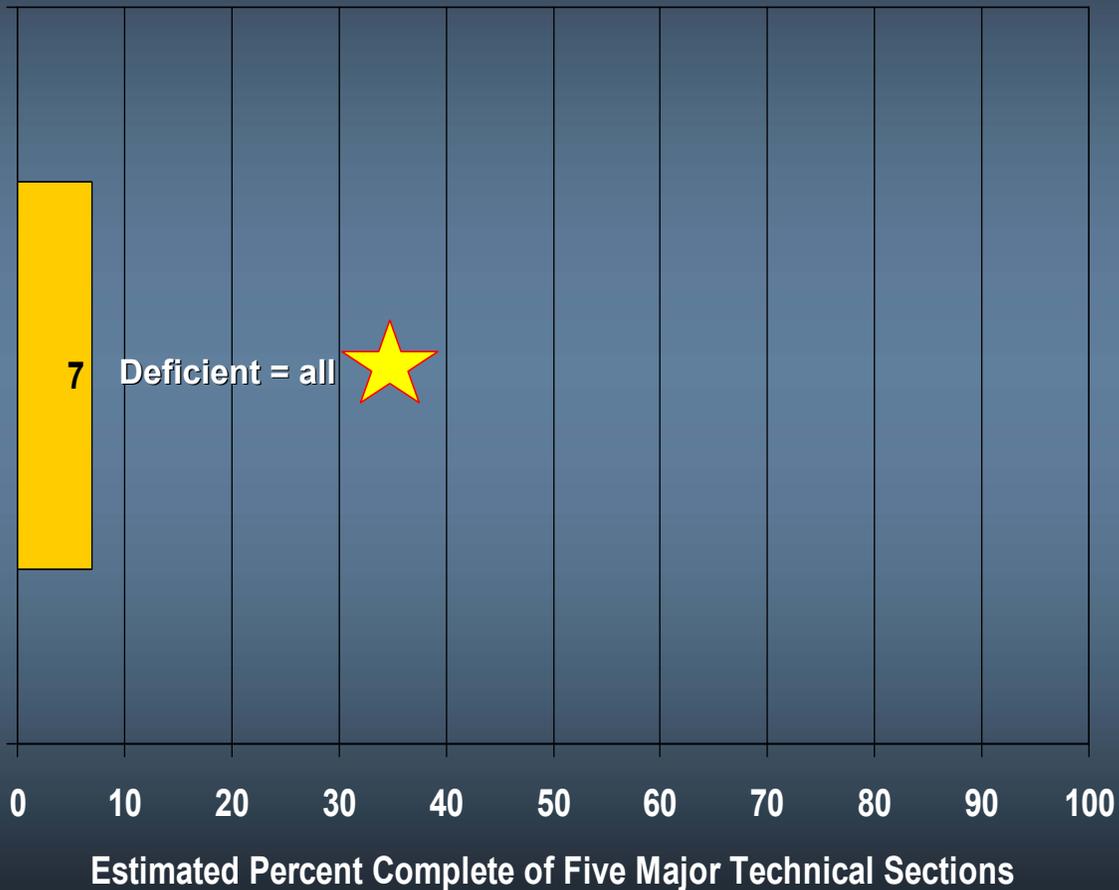
\* = excludes Atlantic salmon HFS, EFF and TAS supportive work  
 # = excludes short-term studies that may be applicable



# Approval Progress for SE-MARK<sup>®</sup> Immersion



Mass-marking of calcified tissue in larval fish





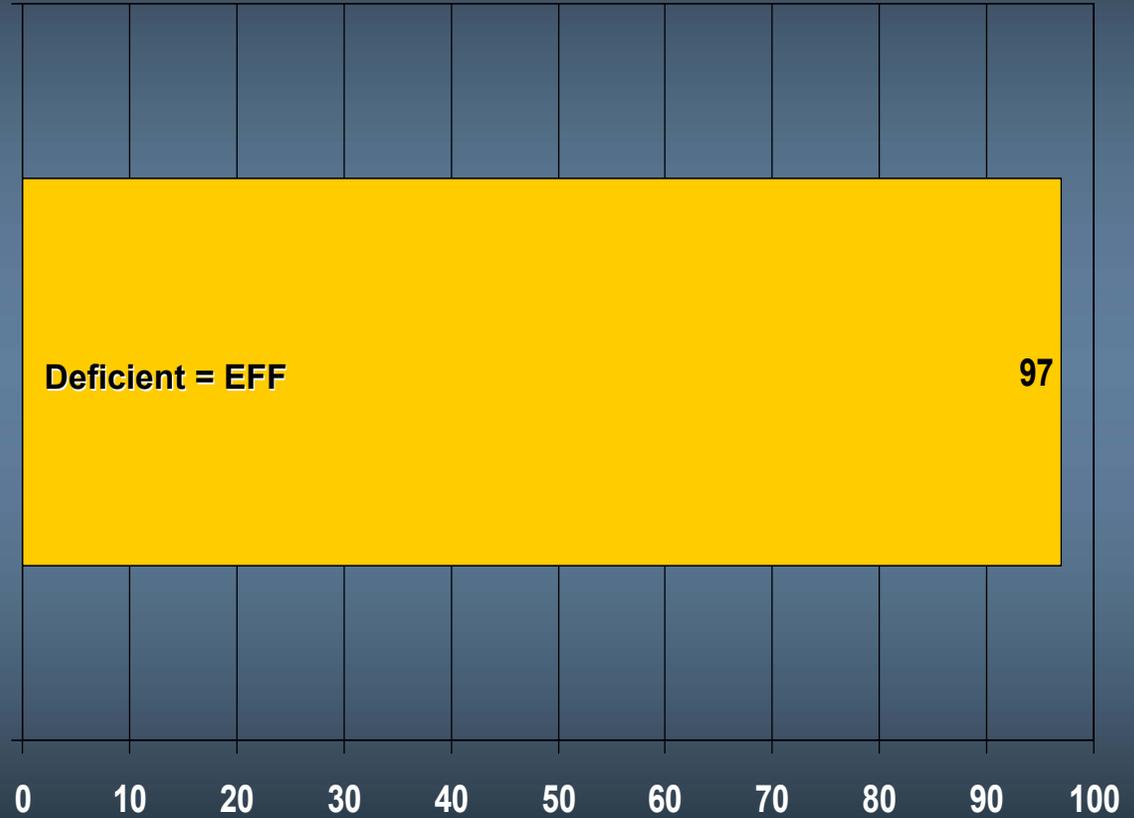
# Approval Progress for Formalin



Saprolegnia in all FW fish

Deficient = EFF

97



Estimated Percent Complete of Five Major Technical Sections



# Approval Progress for CuSO<sub>4</sub>



Ichthyophthirius in channel catfish

Deficient = ES

87

Ichthyophthirius in all other FW fish

Deficient = ES & TAS

73

Saprolegnia in all FW fish eggs

Deficient = ES, TAS & **EFF**

50



BGD in all FW fish

Deficient = ES, TAS & **EFF**

53



External columnaris in all FW fish

Deficient = ES, TAS & **EFF**

53



0 10 20 30 40 50 60 70 80 90 100

Estimated Percent Complete of Five Major Technical Sections



# Approval Progress for KMnO<sub>4</sub>



External columnaris in channel catfish

Deficient = all

45



External columnaris in all other FW fish

Deficient = all

34



BGD in FW salmonids

Deficient = all

31



CWD in FW salmonids

Deficient = all

31



External parasites in FW fish,  
and control of mortalities from same

Deficient = all

31



0 10 20 30 40 50 60 70 80 90 100

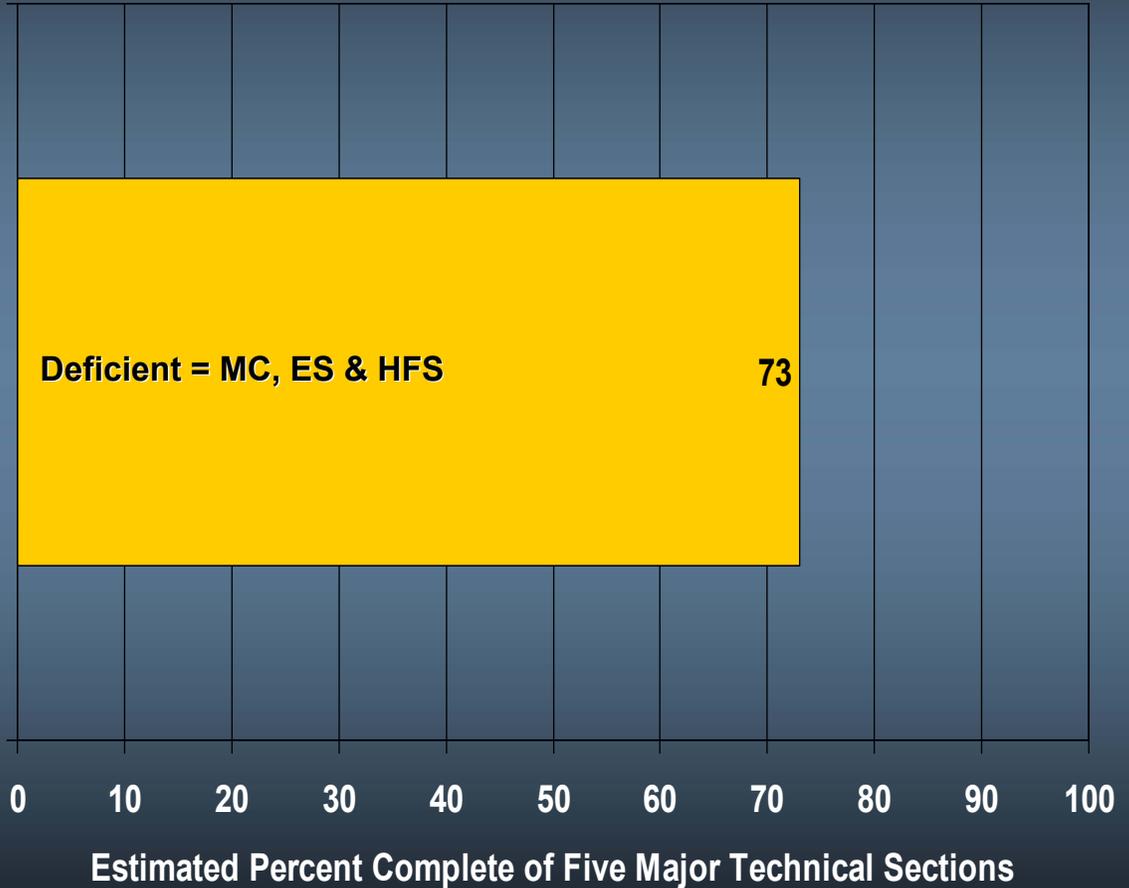
Estimated Percent Complete of Five Major Technical Sections



# Approval Progress for Erythromycin

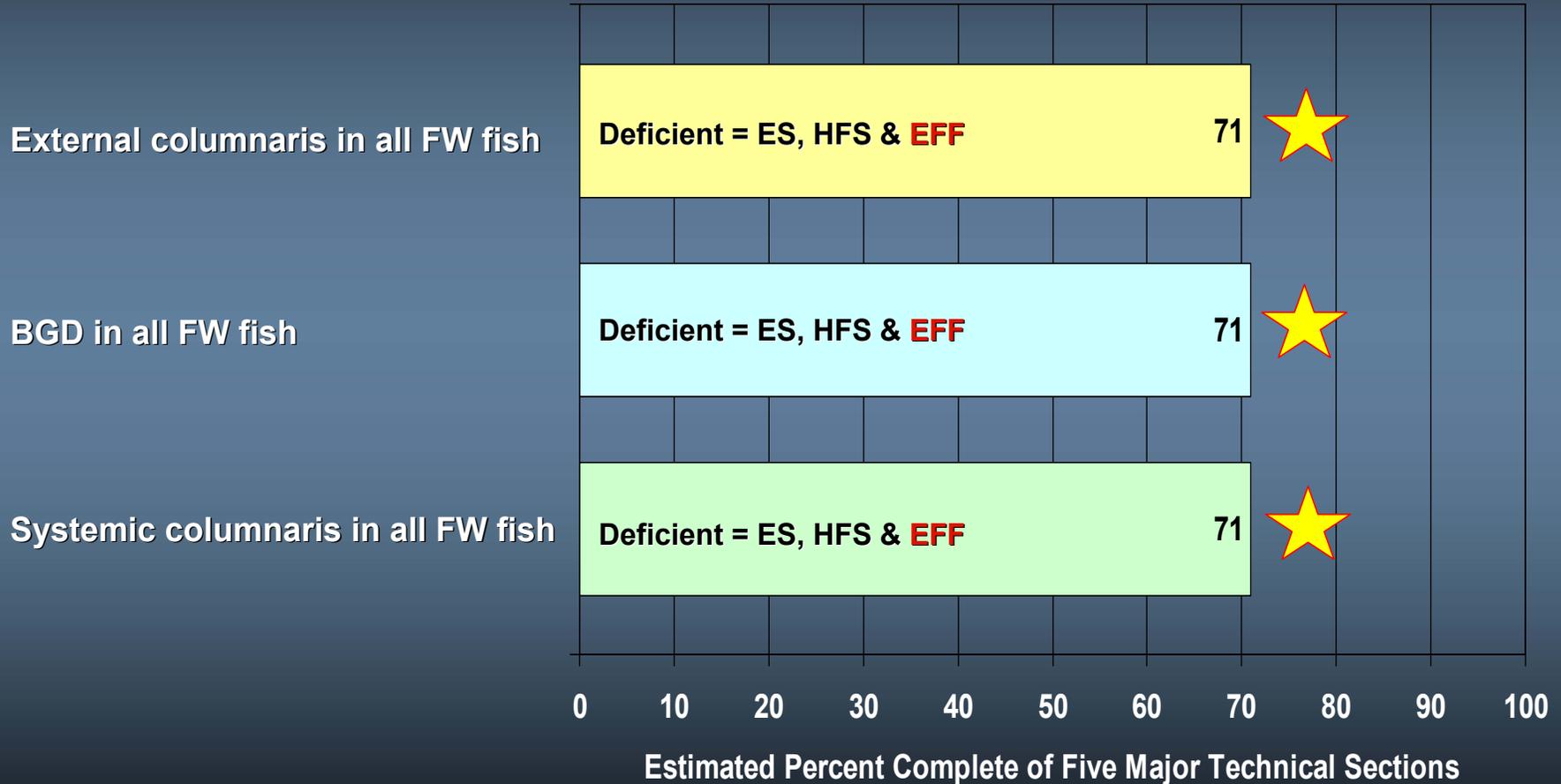


BKD in FW salmonids





# Approval Progress for Immersion OTC





# Approval Progress for 17 $\alpha$ -Methyltestosterone

Masculinization of early life-stage female tilapia

Deficient = MC, ES, **EFF** & TAS 55



Gender manipulation in selected finfish (e.g., salmonids, percids & ornamentals)

Deficient = MC, ES, **EFF** & TAS 46



Estimated Percent Complete of Five Major Technical Sections



# Approval Progress for Crude Carp Pituitary



Spawning Aid for all FW fish

